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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/611,220 | 07/06/2000 | Scott Arouh | DIA 0002P | 4817 |

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Attention William C Fuess
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| EXAMINER |
|---|
| ALLEN, MARIANNE P |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/611,220 | Applicant(s) AROUH ET AL. | |
|---|---|---|---|
| | Examiner Marianne Allen | Art Unit 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *9,10,14 and 15* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Applicant is advised that the response filed 1/17/02 (Paper No. 3) was damaged from the United States Postal Service irradiation process. See attached information.

### *Election/Restrictions*

Claims 1-8, 11-13, and 16-26 have been cancelled. Claims 9-10 and 14-15 are pending.

Applicant's election without traverse of Group IV, claims 10 and 14-15, in Paper No. 3 is acknowledged. Claims 14 and 15 have been examined only with respect to their dependence on claim 10 as acknowledged by applicant.

Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3.

### *Information Disclosure Statement*

Applicant is encouraged to file an information disclosure statement.

### *Specification*

There appears to be text missing from pages 61-62 of the specification. The bottom of page 61 is blank and the top of page 62 is blank. The sentences bordering this section are fragments. Clarification is requested.

### *Claim Rejections - 35 USC § 112*

Claims 10 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 is directed to a method of predicting an optimal drug dosage and/or drug efficacy for a particular individual patient in respect of genomic data, including alleles and/or characteristic SNP patterns. The method requires numerous examples of (i) genomic data including alleles and/or characteristic SNP patterns, and corresponding (ii) historical drug dosage results including optimal drug dosages, for a multiplicity of patients. The specification does not provide the information required by either (i) or (ii) nor does it reference any sources of such information. The specification does not provide any working examples of the method. It is believed that the information required to practice the invention is not available (and does not exist) as these correspondences between an allele/SNP and an optimal drug dosage have not been determined for numerous alleles/SNPs or a multiplicity of patients with respect to particular alleles/SNPs. The specification fails to provide guidance as to how to obtain the information required by the claimed method. As such, one would not be able to practice the claimed invention without undue experimentation.

In support of this position, the examiner relies upon the following references.

For example, Layton et al. investigates whether the therapeutic response of rheumatoid arthritis patients to D-penicillamine is associated with polymorphisms in genes of the glutathione-S-transferase (GST) supergene family. A poor therapeutic response was associated with a particular genotype. However, no optimal dosage information for this particular drug was determined nor discussed, only a likelihood that a patient would or would not respond this particular drug. The reference itself notes on page 43 (left column) that there is little data on other genes that might influence the therapeutic reponse in rheumatoid arthritis and that HLA typing (which is encompassed by genomic data in the absence of a particular definition) is not

helpful in predicting the response to parenteral gold therapy (unspecified whether for a optimal drug dosage).

For example, Fullerton et al. investigates apolipoprotein E variation in populations and the association with cardiovascular disease and Alzheimer's disease risk. Different polymorphisms are known to be associated with certain physiological effects. (See page 882, left column, first complete paragraph.) However, there is no indication that the optimal response of different drugs for these conditions are known or have been determined, nor that they have been associated with a particular allele/SNP.

Fullerton et al. also demonstrates the complexity and the difficulty in linking allele/SNP patterns to disease. (See discussion.) Collin (Human Heredity, 2000) also discusses the challenges of mapping genes for complex traits. The art's inability to do this much raises the burden to applicant to provide guidance in obtaining the necessary information to practice the claimed invention.

Judson et al. (Pharmacogenomics, February 2000) reviews the predictive power of haplotypes in clinical response. This is a new field and the information required by the claimed method is not available. See at least pages 23-24, section 2.7 and 3.0.

Furthermore, it is noted that one practicing the instant invention would not be able to further mine the patient data of the above literature (should additional treatment details pertinent to the claimed invention even have been recorded) as this confidential medical information would not be available.

Claims 10 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 are indefinite for depending upon cancelled claims 11-13. These claims should be amended to depend only from claim 10, the elected method.

Claim 10 is confusing in reciting "optimal drug dosage." With the exception of a drug dosage to exert optimal efficacy the claim is unclear what the predicted drug dosage is optimal for. Furthermore, the claims are confusing in not requiring that the data input for drug dosages corresponds to the intended optimal drug dosage of the preamble. That is, the input appears to encompass optimal drug dosages for different effects.

Claim 10 is confusing in reciting "genomic data, including alleles and/or characteristic SNP patterns." The claim does not make clear what genomic data beyond alleles and/or characteristic SNP patterns are encompassed. The specification does not set forth the metes and bounds of what this genomic data is intended to encompass. Furthermore, it is not known from the claim what the SNP patterns are characteristic for or what defines a characteristic SNP pattern. Note that the alleles and/or SNP patterns are not required to be in any way associated with the drug dosage results. That is, the allele could be concerned with hair color and the drug dosages concerned with optimal aspirin dosage for headache relief. The term "corresponding" in line 7 does not provide a clear link as to what is corresponding other than the data being for the same patient for (i) and (ii).

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
April 19, 2002